

CLAIMS

What is claimed is:

- 5 1. A method for determining a cardiac shock strength, comprising the steps of:
- (a) sensing a change with respect to time in a T-wave of an electrical cardiac signal;
- (b) delivering a test shock by:
- 10 (i) delivering a test shock at a test-shock strength and at a test-shock time relating to sensing the change with respect to time in the T-wave; and
- (ii) sensing for cardiac fibrillation; and
- (c) if fibrillation is not sensed, repeating step (b) at the test-shock strength
- 15 and at a different test-shock time relating to the change in the T-wave; and
- (d) if fibrillation is sensed, setting the cardiac shock strength as a function of the test-shock strength.
- 20 2. The method of claim 1, wherein the change with respect to time is a change in amplitude.

3. The method of claim 1, wherein the change with respect to time is selected from the group consisting of a finite difference, an ordinary derivative, a directional derivative, a gradient, a partial derivative, an implicit differential, a variance calculation, a bounded variation calculation, a radial displacement vector, and a tangent vector approximation.

4. The method of claim 1, wherein the change with respect to time is an extreme value calculated by a method selected from the group consisting of a finite difference, an ordinary derivative, a directional derivative, a gradient, a partial derivative, an implicit differential, a variance calculation, a bounded variation calculation, a radial displacement vector, and a tangent vector approximation.

5. The method of claim 1, wherein the change with respect to time is a maximal value calculated by a method selected from the group consisting of a finite difference, an ordinary derivative, a directional derivative, a gradient, a partial derivative, an implicit differential, a variance calculation, a bounded variation calculation, a radial displacement vector, and a tangent vector approximation.

6. The method of claims 2-5, wherein the change with respect to time is a derivative of T-wave amplitude with respect to time.

7. The method of claims 2 -5, wherein the change with respect to time is a derivative of T-wave amplitude with respect to time selected from the group consisting of the first derivative, second derivative, third derivative, and nth derivative.

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8. The method of claim 7, wherein the change with respect to time is the first derivative of T-wave amplitude with respect to time.

9. The method of Claim 1 in which test-shock times are selected in relation to the maximum of the first derivative of the T-wave with respect to time.

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10. The method of claim 1, wherein step (b) is performed in native rhythm of the heart, and wherein the test-shock time is further based on a sensed QRS complex of the cardiac signal.

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11. The method of claim 1, wherein step (b) is performed in atrial-paced rhythm of the heart, and wherein the test-shock time is further based on a sensed QRS complex of the cardiac signal.

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12. The method of claim 1, wherein step (b) is performed in ventricular-paced rhythm of the heart, and wherein the test-shock time is further based on a pacer spike.

13. The method of claim 1, wherein step (b) is performed in
atrioventricular-paced rhythm of the heart, and wherein the test-shock time is
further based on a ventricular pacer spike.

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14. The method of claim 1, wherein the test-shock time is recalculated
in accordance with step (a) and (b)(i) if fibrillation is not sensed.

15. The method of claim 1, wherein each test-shock time is
predetermined.

16. The method of claim 1, wherein step (b) is repeatable a maximum
number of times, and wherein if fibrillation is not sensed at the maximum
number, a therapeutic cardiac shock strength is set as a value greater than the test-
shock strength.

17. The method of claim 1, wherein step (b) is repeatable a maximum
number of sequence times, and wherein if fibrillation is not sensed at the
maximum number, the test-shock strength is changed by an amount and steps b-c
are repeated in a new sequence.

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18. The method of claim 17, wherein the changed amount is based on at least one of the outcomes from a previous sequence of test shocks.

19. The method of claim 17, wherein the changed amount is
5 determined using a method based on at least one of the outcomes from the previous sequence of test shocks.

20. The method of claim 17, wherein the changed amount is
determined using a method based on at least one of the outcomes from the
10 previous sequence of test shocks and taken from the group of methods consisting of including “up-down” and Bayesian methods.

21. The method of claim 20, wherein, if fibrillation is not sensed at a
predetermined minimum shock strength, further comprising the step of setting the
15 cardiac shock strength at the predetermined minimum shock strength.

22. The method of claim 17, wherein the changed amount is increased.

23. The method of claim 17, wherein the changed amount is a function
20 of the test-shock strength.

24. The method of claim 17, wherein the changed amount is a
predetermined value.

25. The method of claim 1, wherein the cardiac shock strength is a function of the lowest test-shock strength that does not induce fibrillation.

5 26. The method of claim 25, wherein the function is 5J more than the lowest test-shock strength that does not induce fibrillation.

27. A method for determining a cardiac shock strength for a medical device connected to a patient and capable of delivering a shock, comprising the steps of:

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(a) delivering a set of test shocks with the device to the patient, each member of the set comprising the sub steps of:

(i) sensing an electrogram from the patient;

(ii) detecting the maximum derivative of a T-wave of the electrogram;

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(iii) delivering a test shock to the patient at a test-shock strength and at a test-shock time relating to the maximum derivative of the T-wave;

(iv) sensing for induction of cardiac fibrillation; and

(v) if fibrillation is not sensed in step a(iv), then repeating sub-steps a(i-iv) at the test-shock strength up to a predetermined

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maximum set number, each member of the set having a
different test-shock time relating to the maximum derivative of
the T-wave; and

- (b) if fibrillation is not sensed in step (a) after the maximum set number,
then repeating step (a) at a lower test-shock strength; and
- (c) if fibrillation is sensed in step (a), then defibrillating the patient and
setting the cardiac shock strength as a predetermined function of the
test-shock strength that induced fibrillation.

28. A method for determining an optimal programmed first-shock
strength of an implantable cardioverter defibrillator, comprising the steps of:

- (a) delivering a set of test shocks having a predetermined maximum
number of members with the cardioverter defibrillator to the patient,
each member of the set comprising the sub steps of:

- (i) sensing an electrogram from the patient;
- (ii) differentiating the electrogram;
- (iii) detecting the maximum of the derivative with respect to time
of a T-wave of an electrogram;
- (iv) delivering a test shock to the patient at a test-shock strength
and at a test-shock time relating to the maximum of the
derivative with respect to time of the T-wave;

- (v) sensing for an induction of cardiac fibrillation; and
- (vi) if fibrillation is not sensed in step a(v), then repeating sub steps a(i-v) at the same test-shock strength up to a predetermined maximum set number, each member of the set having a different test-shock time relating to the maximum of the derivative of the T-wave with respect to time; and
- (b) if fibrillation is not sensed in step (a) after the maximum set number, then repeating step (a) at a lower test-shock strength; and
- (c) if fibrillation is sensed in step (a), then defibrillating the patient and setting the programmed first-shock strength of an ICD at a predetermined higher level than the test-shock strength that induced fibrillation.

29. A method for determining an optimal programmed first-shock strength of an implantable cardioverter defibrillator, comprising the steps of:

- (a) delivering a set of up to five test shocks with the cardioverter defibrillator to the patient, each test shock member of the set of test shocks comprising the sub steps of:
 - (i) sensing an electrogram from the patient;
 - (ii) differentiating the electrogram;

- (iii) detecting the maximum of the first derivative with respect to time of a T-wave of an electrogram;
 - (iv) delivering a test shock to the patient at a test-shock strength and at a test-shock time relating to the maximum of the first derivative of the T-wave with respect to time;
 - (v) sensing for an induction of cardiac fibrillation; and
 - (vi) if fibrillation is not sensed in step a(v), then repeating sub steps a(i-v) at the same test-shock strength up to and including the last of up to five test shocks, each test shock member of the set of test shocks having a different test-shock time relating to the maximum of the first derivative of the T-wave with respect to time; and
- (b) if fibrillation is not sensed in step (a) by the last of up to five test shocks , then repeating step (a) at a lower test-shock strength, to deliver at least one additional set of up to five test shocks; and
- (c) if fibrillation is sensed in step (a), then:
 - (i) defibrillating the patient with the implantable cardioverter defibrillator; and
 - (ii) setting the optimal programmed first-shock strength of an ICD of the implantable cardioverter defibrillator at a predetermined

higher level than the test-shock strength at which fibrillation was induced.

5 30. A method for determining an optimal programmed first-shock strength of a first therapeutic shock of an implanted cardioverter defibrillator relative to the upper limit of vulnerability, the implanted cardioverter defibrillator having at least one sensing electrode and at least one shocking electrode, comprising the steps of:

- 10 (a) setting an initial test-shock strength, four offset times, and a shock strength decrement;
- (b) delivering a set of up to four test shocks with the implantable cardioverter defibrillator to the patient, each test shock member of the set of test shocks comprising the sub steps of:
- 15 (i) sensing an electrogram from the patient;
- (ii) detecting at least one predetermined base timing point prior to the T-wave of the electrogram;
- (iii) differentiating the electrogram with respect to time;
- (iv) detecting at least one maximum of the first derivative with respect to time of a T-wave of the differentiated electrogram;

- (v) measuring at least one base time interval from the at least one base timing point to the at least one maximum of the first derivative with respect to time of a T-wave;
- (vi) delivering a test shock to the patient at the test-shock strength and at a test-shock time corresponding to the base time interval plus one of the offset times;
- (vii) sensing for an induction of cardiac fibrillation for a predetermined sensing time period; and
- (viii) if fibrillation is not sensed in step b(vii), then repeating sub steps b(i-vii), at the same test-shock strength, up to the fourth test shock, each test shock member of the set of test shocks having a different test-shock time corresponding to a base time interval plus an offset time; and
- (c) if fibrillation is not sensed in step (b) by the fourth test shock, then repeating step (b) at a lower test-shock strength corresponding to the shock strength decrement, to deliver at least one additional set of up to four test shocks; and
- (d) if fibrillation is sensed in step (b), then:
 - (i) defibrillating the patient; and
 - (ii) setting the programmed first-shock strength of the implantable cardioverter defibrillator at a predetermined higher level than

the weakest test-shock strength at which fibrillation was not induced, which test-shock strength represents the upper limit of vulnerability.

5 31. The method of claim 30, further comprising the step, after step (d), of repeating steps (c) and (d) a specified number of times.

32. The method of claim 30, wherein the sensing and detecting steps are implemented entirely with signals obtained from implanted electrodes.

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33. The method of claim 32, wherein at least one implanted electrode is an intracardiac electrode.

34. The method of claim 32, wherein at least one implanted electrode
15 is an intravascular electrode.

35. The method of claim 32, wherein at least one implanted electrode is a subcutaneous electrode.

36. The method of claim 32, wherein at least one implanted electrode is a submuscular electrode.

37. The method of claim 32, wherein at least one implanted electrode is an epicardial electrode.

38. The method of claim 30, wherein at least one electrode is externally disposed.

39. The method of claim 30, wherein the initial shock strength is a sufficiently physiologically high energy value that it is not likely to cause fibrillation.

40. The method of claim 30, wherein the initial shock strength is in the range of 5-30 J.

41. The method of claim 30, wherein the initial shock strength is in the range of 10-15 J.

42. The method of claim 41, wherein the initial shock strength is 15 J.

43. The method of claim 30, wherein
- (a) the implantable cardioverter defibrillator telemeters to a programmer
 - i) a plurality of electrograms,
 - 5 ii) the differentiated electrogram,
 - iii) the base timing point determined in claim 30 (b) (ii),
 - iv) the timing point determined by maximum of the derivative of a T-wave claim 30 (b) (iv), and
 - v) the base time interval in claim 30 (b) (v),
 - 10 (b) the programmer displays on a computer screen a plurality of one or more surface ECG leads and one or more signals taken from electrograms, differentiated electrograms, and timing points and timing intervals telemetered from the implantable cardioverter defibrillator ; and
 - 15 (c) an operator views the screen; and
 - (d) if the operator confirms the timing of timing points indicated in (a) (iii) and (a) (iv) of the present claim using a programmer-input device (such as a mouse, trackball, or touch-screen pen), the implantable cardioverter defibrillator delivers the test shock in claim 30 (b) (vi);
 - 20 and

- (e) if the operator does not confirm the timing of timing points indicated in (a) (iii) and (a) (iv) of the present claim, the operator adjusts the timing of one of these points on the programmer (using a computer input device such as a mouse, trackball, or touch-screen pen), and
- 5 (f) the programmer transmits the adjusted values of these timing points via telemetry to the implantable cardioverter defibrillator, and
- (g) the implantable cardioverter defibrillator uses these adjusted timing points to calculate adjusted base time interval and test-shock time corresponding to the adjusted base time interval plus one of the offset
- 10 times; and
- (h) the implantable cardioverter defibrillator delivers the test shock in claim 30 (b) (vi) at the adjusted test-shock time.

44. The method of claim 30, wherein the number of T-wave shocks

15 and their corresponding offset times are functions of both the location of pacing electrode and the configuration of the electrodes used for defibrillation.

45. The method of claim 30, wherein the offset times are less than one

half the time duration of the T-wave.

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46. The method of claim 30, wherein the offset times are less than 100 milliseconds absolute value.

47. The method of claim 46, wherein the offset times are less than 50 milliseconds absolute value.

48. The method of claim 46, wherein the offset times are less than or equal to 40 milliseconds absolute value.

49. The method of claim 46, wherein the offset times are between 0 and 40 milliseconds absolute value.

50. The method of claim 49, wherein at least one offset time is a positive value, to thereby be adapted to deliver a test shock after the maximum of the first derivative of the T-wave with respect to time.

51. The method of claim 49, where in at least one offset time is a negative value, to thereby be adapted to deliver a test shock before the maximum of the first derivative of the T-wave with respect to time.

52. The method of claim 49, wherein one offset time is 0, to thereby be adapted to deliver a test shock substantially at the maximum of the first derivative of the T-wave with respect to time.

5 53. The method of claim 49, wherein at least one offset time is negative and at least one offset time is positive, to thereby be adapted to deliver at least one test shock after the maximum of the first derivative of the T-wave with respect to time and at least one test shock before the maximum of the first derivative of the T-wave with respect to time.

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54. The method of claim 49, wherein a first offset time is 0, a second offset time is -20 milliseconds, a third offset time is -40 milliseconds, and a fourth offset time is +20 milliseconds.

15 55. The method of claim 49, wherein a first offset time is 0, a second offset time is +20 milliseconds, a third offset time is -20 milliseconds, and a fourth offset time is +40 milliseconds.

20 56. The method of claim 49, wherein there are three test shocks with a first offset time of 0, a second offset time of +20 milliseconds a third offset time of -20 milliseconds.

57. The method of claim 30, wherein the offset time in a set are constant.

5 58. The method of claim 30, wherein the offset time in a set are variable

59. The method of claim 58, further comprising the step of adjusting the offset time within a set.

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60. The method of claim 30, wherein the offset time in each set are identical to offset times in other sets.

61. The method of claim 30, wherein the offset time in at least one set
15 vary relative to offset time in at least one other set.

62. The method of claim 61, further comprising the step of adjusting the offset time of at least one step relative to the offset time of at least one other step.

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63. The method of claim 30, wherein the shock strength decrement is in a range of 1-10 J.

5 64. The method of claim 63, wherein the shock strength decrement is in a range of 2-5 J.

65. The method of claim 64, wherein the shock strength decrement is 5 Joules.

10 66. The method of claim 30, wherein the shock strength decrement is a constant value.

67. The method of claim 30, wherein the shock strength decrement is a variable value.

15 68. The method of claim 67, wherein the shock strength decrement is about 5 J for test-shock strengths of greater than or equal to 10 J, and wherein the shock strength decrement is about 2 J for test-shock strengths of less than or equal to 5 J.

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69. The method of claim 30, wherein the predetermined sensing time period of step (b) (vii) is 1–10 seconds.

70. The method of claim 30, wherein a waiting period is initiated after the sensing period of step (b)(vii) and prior to repeating sub steps b(i-vii) at the same shock strength.

71. The method of claim 70, wherein the waiting period is about 1 minute.

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72. The method of claim 30, wherein a waiting period is initiated after the sensing period of step (b) (vii) and prior to repeating sub step 18(b) at a lower shock strength.

73. The method of claim 72, wherein the waiting period is about 1 minute.

74. The method of claim 30, wherein step (d) further comprises the sub-step of storing the shock value, plus the shock decrement value in the memory of the device as the defibrillation threshold energy .

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75. The method of claim 30, wherein step (b) is accomplished when the heart is in its native rhythm and wherein the base timing point is chosen in relation to timing of the QRS complex.

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76. The method of claim 75, wherein the base timing point is the minimum time derivative of the QRS complex.

77. The method of claim 75, wherein the base timing point is the maximum or minimum time derivative with the greatest absolute value of the QRS complex.

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78. The method of claim 75, wherein the base timing point is the maximum time derivative of the QRS complex.

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79. The method of claim 75, wherein the base timing point is the maximum value of the QRS complex.

80. The method of claim 75, wherein the base timing point is the minimum value of the QRS complex.

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81. The method of claim 75, wherein the base timing point is the maximum or minimum of greatest absolute value of the QRS complex.

5 82. The method of claim 30, wherein step (b) is accomplished when the heart is in its paced rhythm, further comprising the step, performed before step (b)(i), of pacing the heart and wherein the base timing point is chosen in relation to the timing of the pacer spike.

10 83. The method of claim 82, wherein the base timing point is the pacer spike.

84. The method of claim 82, wherein the heart is paced at a cycle length of 500 milliseconds.

15 85. The method of claim 30, wherein steps(b-f) are performed within the implanted cardioverter defibrillator device.

20 86. The method of claim 30, wherein electrograms are acquired from implanted electrodes which are connected to the implanted cardioverter

defibrillator and are transmitted electronically from the implanted cardioverter
defibrillator device to an external programmer, steps (b) (ii)-(v) are performed in
the programmer, - test-shock times are transmitted from the programmer to the
cardioverter defibrillator and test shocks are delivered by the implanted shock
5 electrodes which are connected to the implantable cardioverter defibrillator.

87. The method of claim 30 wherein

- (a) electrograms are acquired from implanted electrodes which are
connected to the implantable cardioverter defibrillator and are
10 transmitted electronically from the implanted cardioverter defibrillator
to an external programmer,
- (b) steps (a) and (b) (ii)-(v) are performed in the programmer,
- (c) a computer screen on the programmer displays one or more signals
taken from a plurality of
 - 15 i) one or more surface ECG leads;
 - ii) a plurality of telemetered electrograms from the implantable
cardioverter defibrillator;
 - iii) the differentiated electrogram;
 - iv) the base timing point determined in claim 30 (b) (ii);

- v) the timing point determined by maximum of the derivative of a T wave claim 30 (b) (iv); and
- vi) the base time interval in claim 30 (b) (v),
- (d) an operator views the screen; and
- 5 (e) if the operator confirms the timing of timing points indicated in (a) (iii) and (a) (iv) of the present claim (using a computer input device such as a mouse, trackball, or touch-screen pen), the test shock times are transmitted from the programmer to the implantable cardioverter defibrillator, which delivers test shocks via the implanted shock
- 10 electrodes; and
- (f) if the operator does not confirm the timing of timing points indicated in (a) (iii) and (a) (iv) of the present claim, the operator adjusts the timing of one of these points (using a computer input device such as a mouse, trackball, or touch-screen pen) resulting in an adjusted base
- 15 time interval; causing
- (g) the programmer to make adjustments in the base time interval and test-shock time corresponding to the base time interval plus one of the offset times; and
- (h) the adjusted test-shock time is transmitted from the programmer to the
- 20 cardioverter defibrillator, and

- (i) the test shocks is delivered from the implantable cardioverter
defibrillator to the implanted shock electrodes which are connected to
the heart.

5 88. The method of claim 30, wherein electrograms are acquired from
electrodes that are implanted in the patient and are connected directly to an
external implant-support device,

- (a) steps (a) and (b) (ii)-(v) are performed in the implant-support device,
- (b) a computer screen on the implant-support device displays one or more
10 signals taken from:

- i) one or more surface ECG leads;
- ii) a plurality of electrograms transmitted from implanted electrodes;
- iii) the differentiated electrogram;
- iv) the base timing point determined in claim 30 (b) (ii);
- 15 v) the timing point determined by maximum of the derivative of a T
 wave in claim 30 (b) (iv); and
- vi) the base time interval in claim 30 (b) (v);

- (c) an operator views the screen; and
- (d) if the operator confirms the timing of timing points indicated in (a)
20 (iii) and (a) (iv) of the present claim, the test shock is delivered from

the external implant-support device to the implanted shock electrodes which are connected to the heart; and

- (e) if the operator does not confirm the timing of timing points indicated in (a) (iii) and (a) (iv) of the present claim, the operator adjusts the timing of one of these points resulting in an adjusted base time interval, causing
- (f) the implant support device to make an adjustment in the test-shock time corresponding to the base time interval plus one of the offset times; and
- (g) test shocks are delivered by the implant-support device to implanted shock electrodes which are connected to the heart.

89. The method of claim 30, wherein electrograms are acquired from electrodes that are implanted in the patient and are connected directly to an external implant-support device, steps (a-d) are performed in the external implant-support device and test shocks are delivered from the external implant-support device to the implanted shock electrodes which are connected to the heart.

90. The method of claim 30, wherein the sensing steps are implemented with a plurality of electrodes, and delivery of a test shock in step

(b)(vi) occurs at a test-shock time relating to the latest-peaking monophasic T-wave detected from any electrode.

5 91. The method of claim 30, wherein the sensing steps are implemented with a plurality of electrodes, and wherein the maximum of the first derivative of the T-wave with respect to time is detected from the electrode in which the derivative of the T-wave reaches its maximum value at the latest time.

10 92. The method of claim 30, wherein at least one implanted electrode is used to sense electrical activity of the heart.

15 93. The method of claim 30, wherein the implantable cardioverter defibrillator is electrically connected to a predetermined arrangement of implanted electrodes and communicates with a programmer via a means selected from the group consisting of radio frequency and telemetry.

20 94. The method of claim 93, wherein the implanted electrodes comprise at least two defibrillation electrodes, at least one of which is intravenously implanted within the heart, at least one implanted sensing electrode, and at least one implanted pacing electrode.

95. The method of claim 82, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by selecting a beat from a plurality of paced beats of a pacing sequence of beats, and a detected maximum derivative of a T-wave is utilized to determine a test-shock time at the end of the
5 pacing sequence.

96. The method of claim 82, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by calculating an average of a plurality of paced beats of a pacing sequence of beats, and the detected maximum
10 derivative of a T-wave is utilized to determine a test-shock time at the end of the pacing sequence.

97. The method of claim 82, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by selecting the next-to-last paced beat of a plurality of paced beats in a pacing sequence of beats, and the
15 detected maximum derivative of a T-wave is utilized to determine a test-shock time at the end of the pacing sequence.

98. The method of claim 82, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by selecting a beat from a
20 plurality of paced beats of a pacing sequence of beats, and a detected maximum

derivative of a T-wave is utilized to determine a test-shock time at the end of the next pacing sequence.

5 99. The method of claim 82, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by calculating an average of a plurality of paced beats of a pacing sequence of beats, and the detected maximum derivative of a T-wave is utilized to determine a test-shock time at the end of the next pacing sequence.

10 100. The method of claim 82, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by selecting the next-to-last paced beat of a plurality of paced beats in a pacing sequence of beats, and the detected maximum derivative of a T-wave is utilized to determine a test-shock time at the end of the next pacing sequence.

15 101. The method of claim 75, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by selecting a beat in native rhythm.

102. The method of claim 75, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by calculating an average value from a plurality of native rhythm beats.

103. The method of claim 75, wherein the step of detecting at least one maximum derivative of a T-wave is accomplished by selecting the last beat of a plurality of native rhythm beats in a sequence of native rhythm beats.

104. The method of claims 101-103, further comprising the initial step of measuring regularity of native rhythm, and if the rhythm is more irregular than a predetermined threshold value,

- a. waiting a predetermined period of time before implementing step (b);
- b. after step (b) (vi), measuring the regularity of native rhythm; and
- c. if the rhythm is sufficiently regular, delivering any T-wave test shock of step (b) (viii); and
- d. if the rhythm is not sufficiently regular, reinitiating the waiting period.

105. The method of claim 30, wherein, if the timing of the maximum of the of the first derivative of the T-wave with respect to time cannot be reliably detected, comprising the additional steps of:

- a. waiting a predetermined period of time; and
- 5 b. repeating the detecting step (b).

106. The method of claim 30, wherein a value of the timing of the maximum derivative T-wave is determined as the average value of a predefined number of beats, and is compared to a value of the timing of the maximum of the first derivative of the T-wave with respect to time measured on the beat prior to delivery of the test shock, and the test shock is aborted if the difference between these two values exceeds a predetermined amount.

107. The method of claim 106, wherein the predetermined amount is 10-100 milliseconds.

108. The method of claim 107, wherein the predetermined amount is 20 milliseconds.

109. The method of claim 31, in which the increment and decrement values are each a function of the test-shock strength.

110. The method of claim 31, in which the specified number of times is
5 between 0 and 10.

111. The method of claim 31, in which the specified number of times is
2 or 3.

10 112. The method of claim 31, in which the specified number of times depends on the outcomes with respect to fibrillation of all previous test shocks delivered.

113. The method of claim 31, further comprising the sub step of
15 waiting a predetermined period of time before repeating step (b) at a higher test-shock strength.

114. The method of claim 55, wherein the predetermined waiting period of time is between about 3 minutes and about 5 minutes.

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115. The method claim 31, wherein a sequence of one or more test shocks is delivered at only one shock strength, and if fibrillation is not detected in step (b) by the fourth test shock, the programmed shock strength of the implantable cardioverter defibrillator is set to a value that is a fixed increment
5 greater than the test shock strength.

116. An apparatus for determining a cardiac shock strength, comprising:

(a) a sensor for sensing the electrical activity of the heart, including the
10 change in the T-wave with respect to time of a cardiac signal and including fibrillation; and

(b) a controller, connected to the sensor , which provides a test shock of a test-shock strength and at a test-shock time relating to the change in the T-wave with respect to time, and to determine the cardiac shock
15 strength as a function of the test-shock strength.

117. An apparatus for determining and delivering a therapeutic cardiac shock, comprising:

(a) a plurality of electrodes, at least one electrode being adapted for
20 sensing cardiac signals and at least one electrode being adapted for delivering shocks to the heart;

- (b) a shock subsystem connected to the at least one electrode for delivering shocks and which is capable of generating test shocks and therapeutic cardiac shocks; and
- (c) a ULV subsystem connected to the shock subsystem and for providing test-shock information to the shock subsystem, the test-shock information including test-shock strength and test-shock time relating to a change in one or more cardiac signals with respect to time, and for determining the shock strength of the therapeutic cardiac shocks as a function of the test-shock strength.

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118. An implantable cardioverter defibrillator system for determining and delivering an optimal programmed first-shock strength based on the upper limit of vulnerability, comprising:

- (a) a plurality of implantable electrodes;
- (b) a shock delivery subsystem, connected to the electrodes; and
- (c) a ULV subsystem comprising:
 - i) a sensor, connected to the electrodes, for sensing the electrical activity of the heart, including a change with respect to time of the T-wave of a cardiac signal and including the presence of fibrillation;
 - ii) a timer connected to the sensor for providing a series of shock times, timed relative to the maximum derivative of the T-wave;

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- iii) a test-shock driver, connected to the timer, for transmitting timing and amplitude information regarding T-wave test shocks;
- iv) a memory unit, connected to the test shock driver and the shock subsystem, for storing programmable values such as pacing cycle length, timing intervals, an initial shock strength, and values for incrementing and decrementing shock strength; and
- v) a controller, connected to the sensor, test-shock driver, and shock subsystem for incrementally varying shock strength and the shock times; whereby the system provides a test shock having a shock strength and shock time selected by the controller;

(d) whereby:

- (i) the shock subsystem delivers an initial test shock to the heart at an initial shock strength and an initial shock time; and if the heart does not fibrillate
- (ii) the system delivers a sequence of test shocks to the heart at the same shock strength and different shock times; and if the heart does not fibrillate
- (iii) the system decreases the shock strength, a strength decrement and delivers test shocks at a sequence of intervals; and if the heart does not fibrillate
- (iv) the system repeats steps (d) (i) – (iii) until the heart fibrillates, whereby the shock strength of the test shock immediately prior to the test shock that induces fibrillation represents the upper limit of

vulnerability, and whereby the optimal programmed first shock strength of an implantable cardioverter defibrillator system is predicted by a fixed increment in relation to the energy level determined to be the upper limit of vulnerability.

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119. The system of claim 118, wherein the system operates when the heart is in its native rhythm.

120. The system of claim 118, wherein the system operates when the heart is paced, the system further comprising a pacer for overdrive pacing the heart, the timer being electrically connected to the pacer and shock times further being timed in relation to one or more pacing spikes from the pacer according to a time delay.

121. The system of claim 118, wherein the programmed shock strength of an implantable cardioverter defibrillator is a value incrementally higher than the upper limit of vulnerability.

122. The system of claim 118, wherein the strength decrement is at least 2 Joules.

123. The system of claim 118, wherein the timer provides at least four time delays comprising time delays measured from a base time, measured from a

predetermined point on an electrogram to a the maximum of the first derivative of the T-wave with respect to time, plus an offset interval ΔT .

124. The system of claim 123, wherein the offset intervals are: 0
5 milliseconds before the maximum derivative of the T-wave, 20 milliseconds before the maximum derivative of the T-wave, 40 milliseconds before the maximum derivative of the T-wave, and 20 milliseconds after the maximum derivative of the T-wave .

10 125. The system of claim 123, wherein the offset intervals are: 0 milliseconds before the maximum derivative of the T-wave, 20 milliseconds before the maximum derivative of the T-wave, 20 milliseconds after the maximum derivative of the T-wave, and 40 milliseconds after the maximum derivative of the T-wave .

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126. The system of claim 118, wherein the electrode arrangement consists of implanted electrodes.

127. The system of claim 126, wherein the implanted electrodes
20 includes at least one intracardiac electrode.

128. The system of claim 126, wherein the implanted electrodes includes at least one intravascular electrode.

129. The system of claim 126, wherein the implanted electrodes includes at least one subcutaneous electrode.

5 130. The system of claim 126, wherein the implanted electrodes includes at least one submuscular electrode.

131. The system of claim 126, wherein the implanted electrodes includes at least one epicardial electrode.

10 132. The system of claim 126, wherein the electrodes include at least one cutaneous electrode.

133. The system of claim 118, wherein a sequence of one or more test
15 shocks are delivered at only one shock strength, and if fibrillation is not detected, the programmed shock strength is set to a value that is a fixed increment greater than the test shock strength.

134. The system of claim 133, in which the energy level is 15 Joules.

20 135. The system of claim 133, wherein the fixed increment is 5 J above the energy level.